Attorney Docket: A39-972-011 November 29, 2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Patent Application of

ROBERT H. SHELTON

Serial No. 09/025,279

Filed: February 17, 1997

For: STANDING ORDER DATABASE SEARCH SYSTEM AND METHOD FOR INTRANET AND INTERNET APPLICATION

GROUP ART UNIT: 2172

EXAMINER: Jean B. FLEURANTIN

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

SUPPLEMENTAL APPEAL BRIEF FOR APPELLANT

HONORABLE COMMISSIONER OF PATENTS
AND TRADEMARKS
Washington, D. C. 20231

Sir:

This Supplemental Brief is in response to the Examiner's Action of August 30, 2001. Such Action, made after filing of Appellant's Brief on Appeal, withdrew the finality of the previous Action, cited a new reference (an article by F. J. Anderson) and instituted a new rejection applying such new reference against certain of the claims. Appellant was given the option of amending the claims for further prosecution or re-instating the Appeal and filing a Supplemental Brief. Appellant has chosen the latter option since no amendment to the claims was

necessary because the newly cited Anderson reference fails to suggest, in combination with the Evans patent of record, the claims against which it has been applied, even if deemed properly combinable with the Evans patent.

Since no amendment has been made to the claims, the Appendix A submitted herewith is a duplicate of that submitted with the original Brief.

This Supplemental Appeal Brief for the above-identified appeal is submitted in accordance with the provisions of 37 CFR 1.193(b)(2)(ii).

REAL PARTY IN INTEREST

The instant application is assigned of record to Allcare Health Management System, Inc. whose address is 100 East 15th Street, Suite 620, Fort Worth, Texas 76102.

RELATED APPEALS AND INTERFERENCES

To the best of Appellant's knowledge and belief, there are no related appeals or interferences.

STATUS OF CLAIMS

There are a total of 81 claims in the instant application, all of which were finally Rejected in the Office Action mailed November 21, 2000.

Claims 1-81 were rejected under 35 USC 103(a) as being unpatentable over Evans United States Patent 5,924,074.

Subsequent to the filing by Appellant of the principal Appeal Brief, the Examiner, by communication mailed August 30, 2001, withdrew the finality of the final action mailed November 21, 2000 and cited a single additional reference "A Security Policy Model for Clinical Information Systems" by Ross J. Anderson.

The present status of the claims is that Claims 1-2,4-43 and 45-81 stand rejected under 35 USC 103(a) as being unpatentable over Evans (U.S. Patent 5,924,074); and Claims 3 and 44 stand rejected as being unpatentable over Evans (U.S. Patent 5.924,074) in view of the Anderson reference, "A Security Policy Model for Clinical Information Systems".

STATUS OF AMENDMENTS

As set forth in Applicant's original Appeal Brief, the following amendments have been filed and entered in the application:

1. A Preliminary Amendment dated September 16, 1998;

2. An Amendment dated June 15, 1999 to which a response was made by Office Action mailed June 6, 2000;

3. A Citation of Prior Art that was mailed by Applicant on October 25, 1999; and

4. An Amendment dated September 5, 2000, to which a response was made finally rejecting the application by Office Action mailed November 21, 2000.

SUMMARY OF INVENTION

As set forth in Appellant's application and in the original Appeal Brief, the present invention is directed to a system and method for individual patients to protect the confidentiality of their medical records. To accomplish this, there is provided a medical data base supervisory control system having at least one data base including medical data individually relating to each of a plurality of patients, internet and/or intranet means including interconnected computers for requesting and accessing the medical data, means for identifying medical data for each of the patients with conditions required for accessing the medical data, such conditions including prior informed consent by the patient about whom such records pertain, and data processing means for comparing the request with conditions required for access of the data and, when the request fails to comply with the required conditions, for overtly denying access to the data.

To carry out the method according to the invention, there is disclosed a method of controlling access to medical data in a medical data base comprising maintaining at least one data base including medical data individually relating to each of a

plurality of patients, identifying medical data for each of the patients with indicia indicative of conditions required for access to the medical data, selectively introducing requests for access to the data through an interconnected computer input terminal, comparing the requests with the required conditions for access, including in the required conditions the prior authorization by the patient about whom such records pertain; and, when the requests fail to comply with the required conditions, automatically denying access to the data.

The system and method also embrace and integrate over internet and/or intranet connections access criteria that may be individualized for each patient or that may be identified with groups of patients.

Important to Appellant's invention is the intentional identification of each patient's record with individualized access criteria conditions that must be met if access to that patient's record is not to be automatically denied. Thus, the broad aspects of the invention are characterized in the two independent claims (i.e., claims 1 and 42) which are set forth in Appendix A. Other aspects of the invention include within the conditions required for access, the prior informed consent by the person about whom the requested medical records pertain.

ISSUES

1. Whether Claims 1-2, 4-43 and 45-81 are obvious and hence unpatentable within the meaning of 35 USC 103(a) over Evans United States Patent 5,924,074.

2. Whether Claims 3 and 44 are obvious and hence unpatentable within the meaning of 35 USC 103(a) over Evans (U.S. Patent No. 5,924,074) in view of Anderson, R. J. (A security policy model for clinical information systems; 6-8 May, 1996) hereinafter, "Anderson".

3. Whether the Anderson reference is properly combinable with Evans without the use of impermissible hindsight.

4. Whether provisions assertively permitting joint access by authorized health care providers is readable as "said conditions required for access of said data and, when said request fails to comply with said conditions, for denying access to said data" (Examiner's assertion at the last three lines of Page 2 of the Office Action of November 21, 2000)(Emphasis added)

5. Whether a system that overtly or assertively denies access unless explicit access conditions are met is anticipated or rendered obvious by a tiered password system that affirmatively provides access when passwords are presented?

6. Whether "it would have been obvious to a person of ordinary skill in the art to have modified the teachings of Evans with the step of data processing means responsive to a request

for patient medical data for comparing said request with said conditions required for access of said data and, when said request fails to comply with said conditions, for denying access to said data . . . ." (Examiner's assertion at lines 9-13 of page 3 of the Office Action of November 21, 2000).

7. Whether the provisions attributed to Evans as quoted at lines 11 et seq of page 3 of the Office Action of 30 August, 2001 reading: "Evans shows the step of the point of care system issues a request for patient data with reference to figure 15a, the patient locator receives the request from the point of care system and attempts to find the patient id for the record having the requested patient data as determined, if no patient id is found the patient locator reports an error at this point the patient data repository may recover from the error by either restarting the process or by ending the process; [which] is readable as data processing means responsive to a request for patient medical data for comparing said request with said conditions required for access to said data)(see figure 15, col. 9, lines 39-48)" (brackets added).

8. Are relationships among patient data patentably indistinct from medical data individually relating to each of a plurality of patients? (Examiner's assertion at third and fourth lines from the bottom of page 4 of the Office Action of November 21, 2000).

9. Whether the term "substantial teaching" is a proper basis for rejecting claims under 35 USC 103(a). (Numerous assertions set forth in the Office Action of November 21, 2000, pages 6-10, and the Office Action of August 30, 2001 pages 4-11).

GROUPING OF CLAIMS

The claims on appeal are separately patentable and do not stand and fall together; and the reasons for the separate patentability are as follows.

It is noted that claims 1 and 42 are independent claims. Claim 1 is directed to a system and is the head claim for a number of dependent claims each defining a system combination believed patentably distinct from the others; and similarly, Claim 42 is directed to a method and is the head claim for a number of dependent claims each defining a method believed patentably distinct from the others.

THE REMAINING CLAIMS ARE ALL DEPENDENT CLAIMS AND ARE SEPARATELY PATENTABLE IN THAT THEY INCLUDE MEANS OR STEPS FURTHER DISTINGUISHING THEM FROM THE EVANS PATENT AND FROM THE ALLEGED COMBINATION OF EVANS AND ANDERSON

Claims 2 and 43 define combinations that are patentably different from the combinations of Claims 1 and 42 respectively in that they further include a means or step for authenticating the identity of the requesting party.

Claims 3 and 44 further include a means or step to prevent access to information concerning medical records by any party without the prior authorization of the patient about whom such records pertain.

Claims 4 and 45 further include a means or step for tentatively identifying records fulfilling criteria specified in said request for medical data.

Claims 5 and 46 include elements of Claims 4 and 45 and additionally include a means or step for authenticating the identity of said patients.

Claims 6 and 47 include the elements of Claims 1 and 42, but additionally qualify the means or step for requesting said medical data in that they further include means or step for indicating what part of the records is desired.

Claims 7 and 48 include the elements of Claims 1 and 42, but additionally qualify the means or step for requesting access by stating that it includes a means or step for indicating the reason that said records are being requested.

Claims 8 and 49 also include the elements of Claims 1 and 42, but further include a means or step for identifying records fulfilling said request with data symbolic of patient identity.

Claims 9 and 50 are dependent to Claims 8 and 49 respectively, but further qualify the means or step for identifying records fulfilling said request by stating that they include data symbolic of medical symptoms or reason for patient visit.

Claims 10 and 51 are also dependent to Claims 8 and 49, but further qualify the means for identifying records fulfilling said request by stating that it further includes data symbolic of types of diagnostic tests performed.

Claims 11 and 52 are dependent to Claims 10 and 51, but further include data symbolic of the attributes, levels or findings indicated within the diagnostic tests.

Claims 12 and 53 are dependent to Claim 8 and 49 but further include data symbolic of modes of treatment or medical services rendered.

Claims 13 and 54 are dependent to Claims 8 and 49, but further include data symbolic of any ancillary services rendered.

Claims 14 and 55 are dependent to Claims 8 and 49, but further include data symbolic of attending physician identity.

Claims 15 and 56 also are dependent to Claims 8 and 49, but further include data symbolic of date of care.

Claims 16 and 57 comprise the elements of Claims 1 and 42, but additionally include a particularizing characterization by indicating that the means for requesting and accessing the medical data include a means or step for indicating a "standing order" that will automatically initiate an attempt to retrieve certain predetermined types of medical data under specific pre-specified circumstances.

Claims 17 and 58 comprise the elements of Claims 1 and 42, but further describe the conditions required for accessing the

medical data as including an indication of the names of each of the parties who's permission must be obtained prior to the release of the medical data.

Claims 18 and 59 are dependent on Claims 17 and 58 respectively, but further characterize the conditions required for accessing the medical data as including an indication of the charge that will be assessed by the holder of the medical data for the part, or in the form, specified by the requesting party.

Claims 19 and 60 further characterize Claims 17 and 58 in stating that the conditions for accessing the medical data include indicating the time following receipt of all approvals that will be required for delivery of the medical data to the requesting party.

Claims 20 and 61 further qualify Claims 1 and 42 by stating that the data base includes a firewall limiting access to searching the data base solely to those who are authorized to do so.

Claims 21 and 62 further characterize the system of Claim 1 and method of Claim 42 by stating that there is included means for producing an indicia of the degree to which patient data match criteria specified in the request therefor.

Claims 22 and 63 extend the system of Claim 1 and method of Claim 42 to include means or step for a patient to grant permission for the release of his/her medical data.

Claims 23 and 64 extend the system of Claim 22 and method of Claim 63 to include billing means (or a step) having access to

the medical data.

Claims 24 and 65 further qualify Claims 22 and 64 in that means or step for a patient to grant permission includes data symbolic of the identity of the patient and data symbolic of the preferred means for contacting the patient to request access to and release of the patient's medical data.

Claims 25 and 66 further qualify the system of Claim 23 and method of Claim 64 in that they further characterize the means for a patient to grant permission as including data symbolic of rules to be followed in the event time elapses before such permission is granted in the case of predetermined types of requests for said medical data.

Claims 26 and 67 are a combination and method, respectively, of the elements of Claims 1 and 42 with means or a step for identifying the party requesting access to the medical data.

Claims 27 and 68 are a combination and method, respectively, of the system of Claim 26 and method of Claim 67 with a means or step for authenticating the identity of each party having right of approval for release of the medical data.

Claims 28 and 69 are a combination and method, respectively, of the system of Claim 27 and method of Claim 68 with a means or step for producing an indicia that all required approvals for release of the medical data have been secured.

Claims 29 and 70 are a combination and method, respectively, of the system of Claim 28 and method of Claim 69 with a means or

step for producing an indicia of the required approvals for the release of the medical data that have not been secured or that have been specifically declined.

Claims 30 and 71 are a combination and method, respectively, of the system of Claim 20 and method of Claim 61 further including data index means and an on-line memory cache.

Claims 31 and 72 are a combination and method respectively, of the system of Claim 30 and method of Claim 71 further including an interface engine enabling a search agent to index the data base of medical data.

Claims 32 and 73 are a combination and method, respectively, of the system of Claim 1 and method of Claim 42 further including means or step for billing the requesting party for a charge related to access to the medical data.

Claims 33 and 74 are a combination and method, respectively, of the system of Claim 1 and method of Claim 42 further including an online memory cache and means or step for delivering medical data to a requesting party including transmitting requested medical data held in digital form to the online memory cache.

Claims 34 and 75 are the system of Claim 33 or method of Claim 74 in which the online memory cache means includes a firewall limiting access to the memory cache exclusively to authorized users.

Claims 35 and 76 are the system of Claim 33 or method of Claim 74 further including a means or step for producing an

indicia that the requested medical data have been received in the online memory cache means and are being held there for download by a requesting party.

Claims 36 and 77 are the system of Claim 34 or method of Claim 75 further including a means or step for the requesting party to enter through the firewall and download the medical data.

Claims 37 and 78 are the system of Claim 1 or method of Claim 42 including a means or step for delivering medical data to a requesting party.

Claims 38 and 79 are the system of Claim 37 or method of Claim 78 further including a means or step for informing the requesting party when medical data is in a non-digital form together with the mode of available delivery.

Claims 39 and 80 are the system of Claim 1 or method of Claim 42 further including an encrypting means or step.

Claims 40 and 81 are the system of Claim 1 or method of Claim 42 further including a security log for retaining an audit trail with regard to communication within the system.

Claim 41 is the system of Claim 1 further including public portions and means for allowing parties to advertise in the public portions of the system.

It will thus be seen that each of Claims 1 to 41 defines a system and that each of Claims 42 to 81 defines a method that is patentably distinct from the others and that accordingly they do

not rise or fall together.

ARGUMENT

I. THE APPEALED CLAIMS 1-2, 4-43 and 45-81 ARE PATENTABLE OVER EVANS PATENT 5,924,074

Introductory Preface: As will be observed from reference to the independent Claims 1 and 42, the claims under appeal define systems and methods characterized by having a data base including medical data individually relating to each of a plurality of patients. In order to avoid denial of access to such data, certain conditions must be met. These include informed consent (e.g., prior authorization) by the person whose medical data is being accessed.

1. The Evans Prior Art Reference:

The principal reference cited against the claims is United States Patent 5,924,074 granted to Jac A. Evans on July 13, 1999 and filed on September 27, 1996. As Evans states, his system automates and simplifies existing methods of patient chart creation, maintenance and retrieval. It creates and maintains all patient data electronically and thus can eliminate or supplement creating and maintaining physical data records. It furnishes healthcare providers with an intuitive, easy-to-use, icon-based interface that enables them to capture and analyze patient data quickly and efficiently. Healthcare providers enter patient data immediately at the point of care and this provides a

complete audit trail for all patient data. In this manner, the EMR (Electronic Medical Record) system disclosed in Evans transforms a patient chart from a static record of a few clinical interactions into a dynamic, real-time comprehensive record linked to an enterprise-wide clinical database.

The Evans system is also said to provide "instant access to patient's electronic medical record by authorized healthcare providers from any geographical location." (Column 14, lines 65-67). It enables complete replacement of physical records and permits healthcare providers such as physicians or nurse practitioners to electronically annotate patient's files and permits concurrent multiple access. It also envisions "patient confidentiality through a tiered password system." (Column 15, lines 21-22)

It will thus be observed that the thrust of the Evans reference is directed to providing Electronic Medical Records (EMR), thus making them more accessible and useful by authorized users; and that other than the above-referenced tiered password system, security considerations within Evans are incidental.

2. Discussion of Patentable Distinctions Over Evans:

Appellant has been unable to find any teaching or suggestion of the conditions required for access to patient data coupled with the overt denial of access as claimed by the claims on appeal. In the context of suggesting how his system facilitates

patient record handling and access, Evans initially makes reference to general access by authorized entities. Subsequently, he refers to tiered passwords for distinguishing between different entities so as to provide differing levels of access; and in that context, he states that "a patient may request restricted access to their data by only certain personnel." (Column 15, lines 29-31). Thus, while a type of restriction is envisioned, it is not a restriction within the purview of Appellant's claimed conditions as that term is properly interpreted when following the authoritative guidelines set forth below.

It is well known that while a claim is not limited to the details of the preferred embodiment set forth in the specification, claims are interpreted in light of the specification. Thus, in *Minnesota Mining & Manufacturing Co v. Johnson & Johnson Orthopaedics* 24 USPQ 2d 1321 (Fed. Cir. 1992) it is said "In defining the meaning of key terms in a claim, reference may be had to the specification, the prosecution history, prior art and other claims . . ." (Page 1327) Similarly, in *Renishaw PLC v Marposs Societa Per Azioni* 48 USPQ 2d 1117 (Fed. Cir. 1998) it is said: ". . . one may look to the written description to define a term already in a claim limitation, for a claim must be read in view of the specification of which it is a part." (Page 1120) (Underscoring added).

Now applying the foregoing principles to interpreting the meaning of the term "conditions" as set forth in Appellant's claims, it will be recalled that in Appellant's specification, the conditions required to avoid denial of access include prior authorization by the patient about whom such record or records pertain. This can be provided either by an initial blanket approval, a prior approval for a limited number of people, or express approval by the patient for access by a party newly requesting access. In all instances there must be a prior approval by the patient before anyone can gain access to his records. That such is not taught by Evans was indicated in the Office Action of June 6, 2000 where, at page 3, it is said "...Evans does not specifically disclose a data processing means responsive to a request for patient medical data for comparing said request with said conditions required for access of said data and, when said request fails to comply with said conditions, for denying access to said data. However, Evans does disclose a method and system comprising the steps of organizing the patient data so as to form a patient record, and retrieving the patient record to access the patient data for use in the care of a patient, and obtaining a patient identifier, locating a patient record corresponding to the patient identifier (which is readable as data processing means responsive to a request for patient medical data for comparing said request with said conditions required for access of said data)" (citing column 3, lines 10-35

of the Evans patent). (Underscoring added).

Appellant has diligently studied the foregoing Examiner's underscored quotation and is unable to find any basis for the assertion that it is "readable as data processing means responsive to a request for patient medical data for comparing said request with said conditions required for access of said data." On the contrary, the patient identifier appears merely to be a convenient tool to assist in locating a patient record and is irrelevant to the question of conditions required to avoid denial of access. Accordingly, it is believed that the Examiner's assertion is in error and should not be sustained.

In the Office Action of August 30, 2001, the first full paragraph on Page 3 appears to be an attempt to provide additional explanation of the foregoing rejection. There, it is stated:

> "Applicant discussed that 'a claimed (sic) is not limited to the details of the preferred embodiment set forth in the specification, claims are interpreted in light of the specification'. However, the claimed conditions required for accessing medical data, 1) has its clear meaning, and 2) does not provide the meaning of 'an initial blanket approval, a prior approval for a limited number of people, or express approval by the patient for access by a party newly requesting access'" (The last part of this passage is found at lines 4-7 of Appellant's

original brief)

Appellant does not understand the relevance of the preceding paragraph. Appellant, in the passage in the immediately preceding sentence states, (page 16, lines 2-4 of the original Brief) ". . the conditions required to avoid denial of access include prior authorization by the patient . ."; and in the immediately succeeding sentence states: "In all instances there must be a prior approval by the patient before anyone can gain access to his records." It should therefore be clear that "an initial blanket approval, a prior approval for a limited number of people, or express approval by the patient for access by a party newly requesting access" is a mere recitation of examples; and that the key words are "conditions" and "include".

The Examiner admits on page 5 of the Office Action of August 3, 2001, that ". . . Evans does not explicitly indicate the step of the data processing means ... for comparing said request with said conditions required for access to said data and, when said request fails to comply with said conditions, for denying access to said data."

The Examiner argues, "Evans implicitly shows the step" in figure 15a, which illustrates how such system functions in those instances in which "the patient locator receives the request ... and attempts to find the patient id for the record" but fails to find such patient id. Examiner attempts to equate Evan's disclosure that in such instances where "no patient id is found,

the patient locator reports an error [from which] the patient data repository may recover ... by either restarting the process or by ending the process." with the privacy system disclosed by Applicant.

This is a gross misreading of Evans, and the Examiner has attempted to equate an error loop that the inventor clearly intended to apply to those instances wherein an alphanumeric identifier was incorrectly entered into the system with a privacy mechanism in Applicant's system that is intended to protect the integrity of the information even in the instance that such identifier was accurately entered. The fact that the system in Evans was unable to process a request for a record whose identifier was entered in error is far from being a privacy mechanism. Clearly, Evans had no such intention, and the Examiner's strained reading of the reference must be rejected. To accept Examiner's argument would be equivalent to believing that the mere fact that when a caller incorrectly dials a person's telephone number the phone system is incapable of connecting that call, negates the novelty of a system that is capable of blocking all incoming calls unless specific pre-conditions are first met. The two frankly have little to do with one another except in the rare instance that the caller places a wrong number.

Further reference to the Office Action of 30 August, 2001 reveals a succession of subsidiary claim rejections based upon

allegations of "substantial teachings" and unsupported assumptions and opinions of the readability of such to features of Appellant's claims. Examples include the statement made in the middle of page 6 of the Office Action: "Evans substantially teaches a system as claimed further includes means for authenticating the identity of the requesting party (thus, the system provides several levels of security for access to patient data, which is readable as the identity of the requesting party." Such examples continue through the middle of page 11. However, Appellant takes exception to these rejections. Since the subsidiary claims are subordinate to independent Claims 1 and 42 whose rejections are unsupportable for the reasons given above and below, patentability of the subordinate claims is also evident for the reasons given with respect to Claims 1 and 42. In addition, rejections based upon grounds such as "substantial teaching" appear to be nothing more than speculation and opinion unsupported by facts and concrete evidence as required by standards set forth in the Authorities cited in Appendix B.

Another example is in the first full paragraph on page 8 of the August 30, 2001 Office Action. There, the Examiner argues that Evan's disclosure of a "patient record [that] includes a patient identifier and at least one data structure including the patient identifier and the data" is readable as "an indication of the names of each of the parties who's permission must be

obtained prior to the release of the such medical data." Once again, this is nonsensical. The mere assigning of a pseudonym to a data element has nothing whatsoever to do with the authorities and permissions associated with such data element. This was not something which Evans ever concerned himself with, and it is a central issue concerning which Appellant's invention is addressed.

Again, in multiple instances on pages 9 and 10, the Examiner equates Evans' inclusion in patient files of "the patient's billing payment and scheduling records" with Applicant's mechanism for charging (e.g., through a billing means) for granting access to said records. The only thing that is remotely the same in these two cases is the use of the word "billing", but Examiner entirely misconstrues both the context and meaning of the word which, in Evans, addresses the historical billing records for procedures which the patient has received; whereas in Applicant's disclosure, it addresses an administrative or inter-departmental charge for the service of disclosing the record to a party requesting them.

On page 11 of the August 30 Office Action, the Examiner suggests that Evan's disclosure as to how his system operates "if the data in the cache is not ready for transfer" (i.e., "the process ends") is readable as permitting a properly credentialed requesting party to enter through the firewall and download said medical data from the memory cache. Once again, the only possible

similarity is the term "memory cache", but the context and orientation of the two systems is totally different. Quite clearly, Evan's system has nothing to do with security, but merely is addressing what happens if the system is not ready when a request is made. Appellant's system addresses what happens if the system **IS** ready when a request is made, but if the person making such request does not have the proper authority to receive the data that **IS** present in the cache. Clearly, by its very disclosure, Evan's system would fail to provide any protection for the data in the memory cache in such instance, whereas the data in Appellant's system would be secure. It is inconceivable in light of this that Examiner could assess the Evan's system to anticipate Appellant's system.

Although the foregoing considerations are deemed to support patentability of Claims 1-2, 4-43 and 45-85, additional support for their patentability is set forth in the following sections and, in particular, Section IV which deals with unobviousness and the fulfillment of a long felt need.

II. CLAIMS 3 AND 44 ARE UNOBVIOUS AND PATENTABLE OVER EVANS PATENT 5,924,074 IN VIEW OF ANDERSON

The second issue relates to the unobviousness and patentability of Claims 3 and 44 over the combination of Evans United States Patent 5,924,074 and Anderson, R. J. "A Security Policy Model for Clinical Information systems."

1. The Evans Prior Art Reference: As set forth above, Evans discloses a system which automates and simplifies existing methods of patient chart creation, maintenance and retrieval. It creates and maintains all patient data electronically and thus can eliminate or supplement creating and maintaining physical data records. It furnishes healthcare providers with an intuitive, easy-to-use, icon-based interface that enables them to capture and analyze patient data quickly and efficiently. Healthcare providers enter patient data immediately at the point of care and this provides a complete audit trail for all patient data. In this manner, the EMR (Electronic Medical Record) system disclosed in Evans transforms a patient chart from a static record of a few clinical interactions into a dynamic, real-time comprehensive record linked to an enterprise-wide clinical database.

The Evans system is also said to provide "instant access to patient's electronic medical record by authorized healthcare providers from any geographical location." (Column 14, lines 65-67). It enables complete replacement of physical records and permits healthcare providers such as physicians or nurse practitioners to electronically annotate patient's files and permits concurrent multiple access. It also envisions "patient confidentiality through a tiered password system." (Column 15, lines 21-22).

It will thus be observed that the thrust of the Evans reference is directed to providing Electronic Medical Records (EMR), thus making them more accessible and useful by authorized users; and that security considerations are incidental.

2. The Anderson Reference: This reference is an article describing a theoretically desirable security policy model which is said to spell out clear and concise access rules for clinical information systems. As stated in the Anderson abstract, "Its effect is to restrict both the number of users who can access any record and the maximum number of records accessed by any user." Thus, its effect is contrary to that of Evans, a first reason why it is not properly combinable with Evans; and, as set forth below, it is quite simply a wish list of desirable characteristics for a medical records system, for it neither alludes to nor describes a workable system. This is even more clear from the author's full report which was referenced in the document cited by the Examiner.

Before addressing specific operational considerations, additional background information should be helpful.

The Anderson reference cited by the Examiner, on page 30, right hand column, lines 21-23 states: [This] "The presentation is of necessity abbreviated, and readers are urged to obtain a the [sic.] full document [upon which it is based] from the BMA or via the web...." This full document, the author's unabbreviated

report, has been accessed and studied by Appellant. It is presented at the following address: http://www.ftp.cl.cam.ac.uk/ftp/users/rja14/policy11.pdf. This unabbreviated report, entitled *Security in Clinical Information Systems* (January 4, 1996 by Dr. Ross J. Anderson), describes both the intent and scope of the analysis. It states on pages 1-2, "The British Medical Association ... asked the author to consider the risks, and to prepare a security policy for clinical information systems.... An information security policy says who may access what information.... To be effective, it needs to be written at the right level of abstraction.... We are not concerned whether a system is made up of a single large mainframe ... or even from thousands of clerks moving pieces of paper around. We are only concerned with the net effect of the information processing."

Anderson continues his explanation as to the nature of the policy on page 9, where he adds: "[The policy's] primary purpose is to help clinical professionals discharge their ethical and legal responsibilities by selecting suitable systems and operating them safely. It seeks to define what kind of systems may prudently be trusted to receive personal health information.... This consists of a compact set of principles that if implemented properly will enforce patient consent in communicating computer systems." Anderson adds on page 18: "We do not insist that security be all in software; we are concerned

with the net effect of all processing, both automated and manual." By contrast, Applicant's system uses algorithms contained in software or controlling the function of hardware carrying out such directives.

Notwithstanding, Anderson makes no effort to indicate any means by which to "properly implement" the policy, other than a few sweeping generalizations, including the following one, found on pages 26-27: "...when working cross-domains, records must be given rather than snatched; access requests should never be granted automatically but need a deliberate action by a clinician" (Underscoring added). This stands in stark contrast to Applicant's claimed systems and methods, wherein one of the explicit objectives is to define systems and methods by which, when certain conditions are fulfilled, serve to intentionally **enable** access requests to be granted automatically. This also contributes to the non-combinability of Anderson with Evans.

Another sweeping generalization by Anderson as to system implementation that would fulfill the privacy policy he outlines in the report and that stands in stark contrast to the system and methods, as proposed by Appellant, appears on page 27. Anderson states: "Systems which contain personal health information on significantly more than 1,000,000 people should not be built." No such prohibition is present in Appellant's system. To the contrary, such an arbitrary limitation on the number of users runs in the opposite direction from Appellant's system, which

endeavors to reach the largest possible number of persons and medical records; yet another reason why Anderson is not properly combinable with Evans.

Similarly, on page 19, Anderson prescribes that "Hospital systems which give all clinicians access to all data should not be connected to networks." By contrast, one of the objects of Appellant's system is to provide all hospitals and all clinicians with the ability to search for records through a single network similar to a search engine such as, for example, Alta Vista with respect to Web pages. As a concession to the inevitability that large inter-connected networks will occur, Anderson states on page 20: "... there will inevitably be mechanisms for clinicians to access records from outside their own care team, even if these are manual ones. These mechanisms need careful design.... The primary control on such threats [to privacy] is notification." Appellant's system precisely represents a carefully designed mechanism to overcome the kinds of threats foreseen by Anderson. It does not rely merely on notification to overcome them, but on a well-conceived system as set forth in the application.

Anderson notes on page 26 that: "In medicine, authority is hierarchical, but tends to be local and collegiate rather than centralized and bureaucratic. If this reality is not respected, then the management and security domains could get out of kilter, and one could end up with a security system which clinicians considered to be a central imposition rather than something

trustworthy under professional ownership and control." Therefore Anderson concludes: "... a single certification authority would be a single point of failure..." The master index and private access server recommended by Appellant are clearly averse to such direction.

But even more fundamental problems exist in the Anderson reference, relating to the very meaning of the term "informed consent". In Appellant's system, (as discussed in detail above),it is clear by the function and operation of the disclosed system precisely what is meant by this term. No such clarity is present in Anderson's detailed report or in the summary article cited by Examiner.

Anderson's detailed report notes on page 3 that "a recent EU Directive obliges the government to prohibit the processing of health data except where the data subject has given his explicit consent.... The basis ethical principle, as stated by both the GMC and the EU, is that the patient must consent to data sharing. Confidentiality is the privilege of the patient, so only he way [sic.] waive it; and the consent must be informed, voluntary and competent."

However, from neither Anderson's article or the full report is it clear as to what he means by the term "informed consent.". For example, Anderson notes on page 3: "Thus, for example, patients must be made aware that information may be shared between members of a care team, such as a general practice or a

hospital department." He also indicates on page 11: "The principle of consent and the rules used to interpret it are well entrenched - they have evolved over centuries of clinical experience, and are supported by data protection law." But he does not state what they are; and so the reader is left without an understanding of just what he envisions.

On page 12, in "Principle 1", Anderson adds: "Each identifiable clinical record shall be marked with an access control list..." In an example that he cites, he notes: "... written consent was obtained at the start of the assessment for information to be shared. In this way, the patients knew whom they were signing up to trusting." On page 13, he clarifies the objective of his policy as follows: "When a patient registers with a practice or otherwise commences a clinical relationship with a care team, and a record is opened for him, he should be given information on the team's access control policy. He must also be given the opportunity to object and request that his record be restricted to one or more named clinicians." In stark contrast, the thrust of Appellant's system is to devise a system addressing the conditions upon which information may be released, transferred or otherwise provided outside the immediate "care team", as suggested by Anderson, both initially and from time-to-time following the commencement date of a particular clinical relationship. Thus it is clear that Anderson's policy is quite different from Applicant's system which is more dynamic, and

subject to post hoc decisions by the patient based upon the precise nature of the request for sharing the record at the time such request is made rather than a prospective determination that covers every circumstance in the same manner, at the time the clinical relationship is commenced.

Anderson's policy indicates (on page 14): "When information is sought by, and may lawfully be provided to, a third party such as a social worker, a lawyer, a police or security officer, an insurance company or an employer, then the information must be provided on paper. This reflects current practice ... records shared between doctors, nurses and social workers were kept on paper rather than on a database because of security concerns." This policy imposes a restriction on the system that Appellant's system expressly seeks to overcome. Moreover, one of the objects of Appellant's system is to maximize the utility of the electronic database since Appellant's disclosure lends itself to many capabilities and a greater degree of informed consent than possible or sought by Anderson's policies or any system of which he was aware in writing his report for the BMA.

The only situations in which Anderson deals with automatically releasing data is in the instance of emergencies, whereas Appellant's system is markedly different, thus providing flexibility - at the direction of the patient - of when such automated release is permitted. Anderson's policy notes on page 15, "The notification requirement thus flows from the principle

of consent.... The feeling among clinicians is that notification should be annually by letter, unless a violation or a suspicious pattern of activity has been detected." This is grossly different from Appellant's system, where informed consent notification can be by a plurality of means, including electronic, automated voice response units and facsimile each time that the records are requested, if so stipulated by the patient. No such possibility is foreseen by Anderson.

The problem with Anderson's policy in contrast to the system disclosed by Appellant is apparent by the following question that appears on page 16 of Anderson's full report: "When a patient observes from his annual notification letter that someone he never consulted has read his record, what should he do?" This unfortunate circumstance would be avoided in its entirety by the use of Appellant's claimed system which if so stipulated by the patient, can affirmatively deny access unless informed consent has been obtained. In Appellant's system, such notification would occur before the records were shared, and thus the patient would be able to foreclose such undesired disclosure.

In summary, nowhere in the Anderson reference (or in the unabbreviated report upon which it is based) is there support for stating that it discloses the missing element(s) from Evans, i.e., the affirmative/assertive prevention of access to a patients records as envisioned by, for example, clause (d) of Claim 1 which reads "(d) data processing means responsive to a

request for patient medical data for comparing said request with said conditions required for access to said data and, when said request fails to comply with said conditions, for denying access to said data" (Underscoring added). Moreover, for the reasons set forth above and in the following section, the Anderson reference is not properly combinable with Evans.

III. THE ANDERSON REFERENCE IS NOT PROPERLY COMBINABLE WITH EVANS WITHOUT THE USE OF IMPERMISSIBLE HINDSIGHT.

According to Appellant's understanding, in order for references to be properly combinable, there must be something in the references or in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination. Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company 221 USPQ 481 (Fed. Cir., 1984). Please also see In re Sernaker, 217 USPQ 1 (Fed. Cir., 1983), Page 6. "The lesson of this case appears to be that prior art references in combination do not make an invention obvious unless something in the prior art references would suggest the advantage to be derived from combining their teachings."

Not only do the Evans and Anderson references fail to meet the foregoing authoritative tests, but they are substantially at odds with each other. As stated in the Anderson abstract, "Its effect is to restrict both the number of users who can access any record and the maximum number of records accessed by any user."

Thus, its effect is contrary to that of Evans, a first reason why it is not properly combinable with Evans. Moreover, as mentioned above, Anderson makes no effort to indicate any means by which to "properly implement" his policy, other than a few sweeping generalizations, including the following one, found on pages 26-27: "...when working cross-domains, records must be given rather than snatched; access requests should never be granted automatically but need a deliberate action by a clinician" (Underscoring added). This stands in stark contrast to Evans, further contributing to the non-combinability of Anderson with Evans. And further, as mentioned above, Anderson suggests keeping records on paper to carry out his privacy recommendations, whereas the thrust of Evans is to eliminate such physical data records.

Although the foregoing considerations are deemed conclusively to dispose of the proposed combination, it is evident that still other considerations are applicable. Thus, the Federal Circuit in the case of W. L. Gore and Associates, Inc. V Garlock, Inc. 220 USPQ 303, at 312 states "To imbue one of ordinary still in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." The Federal Circuit cited this Gore case with approval in *In re Zurko*, Fed.

Circuit, 1997 (42 USPQ 2d 1476 at 1479) also noting "In so erring, the Board impermissibly used hindsight to arrive at the claimed invention."

From the foregoing, it is evident that the Anderson reference is not properly combinable with the Evans patent without using appellant's disclosure as a guide and ignoring the fact that Anderson teaches away from Evans. This is impermissible hindsight and not a proper basis for rejection under 35 U.S.C. 103(a). Accordingly, it is respectfully requested that the rejection of Claims 3 and 44 be withdrawn.

IV. PROVISIONS ASSERTIVELY PERMITTING JOINT ACCESS BY AUTHORIZED HEALTH CARE PROVIDERS ARE NOT READABLE AS "SAID CONDITIONS REQUIRED FOR ACCESS OF SAID DATA"

The fourth issue now addressed is whether provisions assertively permitting joint access by authorized health care providers is readable as "said conditions required for access of [to] said data and, when said request fails to comply with said conditions, for denying access to said data" (Examiner's assertion at the last three lines of Page 2 of the Office Action of November 21, 2000 and lines 17-19 of the Office Action of August 30, 2001)(Emphasis added). Appellant has diligently attempted to find some basis for this assertion but has been unable to find any. How can a provision permitting access be interpreted as a condition for denying access? If there is a

sustainable basis for such a conclusion, Appellant would appreciate being advised of same in the Examiner's reply brief. Otherwise, it is believed that such a conclusion is in error and should be overturned.

V. A SYSTEM THAT OVERTLY DENIES ACCESS UNLESS EXPLICIT ACCESS CONDITIONS, INCLUDING PRIOR PATIENT AUTHORIZATION, ARE MET IS NOT ANTICIPATED OR RENDERED OBVIOUS BY A TIERED PASSWORD SYSTEM THAT AFFIRMATIVELY PROVIDES ACCESS WHEN PASSWORDS ARE PRESENTED.

The fifth issue now addressed is: Whether a system that overtly or assertively denies access unless explicit access conditions, including prior patient authorization, are met is anticipated or rendered obvious by a tiered password system that affirmatively provides access when passwords are presented? In addressing this issue, Appellant would show that there is no teaching or suggestion in the Evans reference (or in any other art of which Appellant is aware) that passwords as used by Evans are conditioned upon prior patient authorization. On the contrary, as Evans expresses, "through the use of a tiered password system . . the system provides several levels of security for access . . . For example, a system administrator may have global password access to any patient data . . . whereas physicians may have access only to patient records within their specialty and nurses and staff may have access to only those

patient records within their immediate care." Although Evans states that a patient may request restricted access to their data by only certain personnel, such is not correlated with the foregoing passwords. Accordingly, it is believed evident that the tiered password system as disclosed by Evans does not render obvious the conditions envisioned by Appellant, which conditions require prior affirmative authorization by the patient in order to avoid denial of access.

Passwords in a computerized system function like keys in a hotel. In the latter, there can be keys to an individual room such as given to the bellman who accompanies a hotel guest to his room; keys to all of the rooms located on an entire floor, such as given to the maids who service that floor; and a master key to every room in the entire hotel, such as held by the hotel manager or security personnel. These different sorts of keys have the characteristics of the tiered password system envisioned by Evans, i.e., they allow different locks to always be opened in the same manner, irrespective of the wishes of the guest who occupies the room from time to time. What distinguishes Appellant's system from such a tiered password system is the conditions imposed even on persons with keys to entry. Thus, for example, in Appellant's system, Guest #1 could post a "Do not disturb sign" on his door that would notify anyone - regardless of the nature of their hierarchical key - that they are not allowed to enter the room on that discrete day and time.

Similarly, in Appellant's system, a patient could impose a "Do not share" condition on a particularly embarrassing record that would bar anyone - regardless of the nature of their hierarchical password - that they are not allowed to access the record. Guest #2 in our hypothetical hotel could impose the following condition: No one may enter my room without first informing me what he or she wishes to do each time, and then only with my express written permission to enter. Similarly, Patient #2 could impose the condition that no one may access my records without first providing me with information concerning what record they desire to see and for what purpose, and then only upon receiving my express written permission. Finally, Guest #3 could impose the following condition: "In order for a maid to enter my room, she must receive my express permission or alternatively, for changing my sheets in the morning (but only for such service), if she has received the express permission of the hotel manager if I do not respond to her request on any given day within the first 10 minutes." Thus, Patient #3 could state that only in the event that he is rendered unconscious or in a medical condition where he is unable to respond is the express permission requirement waived, and then only for an accredited emergency room physician. As these examples show, the presence of passwords (keys) - even hierarchically based keys (passwords) - does not provide the capabilities that are present in Appellant's disclosed system. Nowhere in the Evans reference are conditions such as those

illustrated in the foregoing analogy present because it is quite clear that Evans never had any intention whatsoever of providing the kind of capabilities envisioned by Appellant. The addition of the Anderson reference makes no difference to such conclusion.

VI. IT WOULD NOT HAVE BEEN OBVIOUS TO A PERSON OF ORDINARY SKILL IN THE ART TO HAVE MODIFIED THE TEACHINGS OF EVANS WITH THE STEP OF DATA PROCESSING MEANS RESPONSIVE TO A REQUEST FOR PATIENT MEDICAL DATA FOR COMPARING SAID REQUEST WITH SAID CONDITIONS REQUIRED FOR ACCESS OF SAID DATA AND, WHEN SAID REQUEST FAILS TO COMPLY WITH SAID CONDITIONS, FOR DENYING ACCESS TO SAID DATA.

The Examiner asserts at lines 9-13 of page 3 of the Office Action of November 21, 2000 and page 3, lines 19 et seq of the Office Action of August 30, 2001, that "it would have been obvious to a person of ordinary skill in the art to have modified the teachings of Evans with the step of data processing means responsive to a request for patient medical data for comparing said request with said conditions required for access of said data and, when said request fails to comply with said conditions, for denying access to said data . . . ." Other conclusions are also made e.g., in the last three lines of page 5 and the first three lines of page 6 of the Office Action of November 21, 2000 where it is said "It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the teachings of Evans with the step when said

request fails to comply with said conditions, for denying access to said data, because such modification would allow Evans to provide efficiently cost effective (sic) to move data instead of physical records and health care providers, and eliminates the mishandling loss, destruction of patient data typically associated with maintenance of physical data records." (citing col. 14, lines 30-41). (*The foregoing sentence does not seem to make sense but is quoted precisely as written in the Office Action. The parenthetical expression 'sic' is included to indicate that the quotation is precisely as written.*) In this connection, Appellant would respectfully ask how thus modifying Evans would then make it cost effective to move data? Evans already moves data. How could one legitimately visualize that modification of Evans to introduce impediments to moving data could in any way make it more cost effective? The contrary would appear to be true.

Thus, in response to the foregoing conclusions, Appellant avers that such conclusions by the Examiner are unsupported by any implicit or explicit suggestion of, or any real motivation for, or the desirability of such modification, in the Evans patent itself, the Anderson articles, or elsewhere. As such, the conclusions of "obviousness" made by the Examiner are nothing but unsupported opinion, and not proper basis for rejection. In this connection, it is Appellant's understanding that the Examiner is

required to identify where the prior art provides a motivating suggestion for the modification as, for example, in the decision in *In re Jones,* 21 USPQ 2d 1941 (Fed. Cir. 1992) where the court held: "Before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so . . . *In re Fine*, 5 USPQ 2d 1596, 1598-99 (Fed Cir 1988)" [at 1943] (Emphasis Added). "The prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compound." [at 1944] (Emphasis added). Moreover, the courts have advocated that even if the prior art may be modified as suggested by the Examiner, the modification is not obvious unless the prior art suggests the desirability for the modification as, for example, in the decision in *In re Fritch* 23 USPQ 2d 1780 (Fed Cir 1992), where the court held: "Mere fact that prior art may be modified to reflect features of claimed invention does not make modification, and hence claimed invention obvious unless desirability of such modification is suggested by prior art . . ." [at 1780] (Emphasis Added).

As clearly stated by Judge Rich in *In re Soli* 137 USPQ 797, 801: "When, as in the instant case, the Patent Office finds, in the words of 35 U.S.C. 103, 'differences between the subject matter sought to be patented and the prior art,' it may not

without some basis in logic or scientific principle, merely allege that such differences are either obvious or of no patentable significance and thereby force an appellant to prove conclusively that it is wrong." (Underscoring added).

Moreover, it is well settled that an Examiner's speculation or opinion is improper unless supported by **facts**. See *In re Lunsford* 148 USPQ721, 725 where it is said, "Moreover as a matter of law under 35 U.S.C.103, the examiner **must** substantiate his 'suspicions' on the basis of facts drawn from proper prior art. The issue to be resolved requires more than 'suspicions' it requires facts." and "it is not realistic . . . within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. (Emphasis added). Please also see the recent case of *In re Zurko* (59 USPQ2d 1693, Fed. Cir., 2001) in which it was said that "the Board's finding that the prior art teaches, either explicitly or inherently, . . . [was] clearly erroneous." Also, (at page 1697) ". . the Board cannot simply reach conclusions based on its own understanding or experience -- or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.

Appellant further calls attention to the criteria set forth by the Court of Appeals for the Federal Circuit in the case of *In re Rijckaert* 28 USPQ 2d, 1955 (1993). There, the court stated: (1) "in rejecting claims under 35 U.S.C. 103, the Examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant"' (2) "when the PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it **must** indicate where such a teaching or suggestion appears **in the reference**" (Emphasis added); (3) "The mere fact that a certain thing may result from a given set of circumstances is not sufficient . . ."

In further response to the foregoing, Appellant would respectfully show that, despite diligent search, he has been unable to find any teaching or suggestion (**implicit or explicit**) in either the Evans reference or any other art of which he is aware, of the automatic denial of access to a patient's record until a comparison of a request for a patient's record meets conditions a required for access thereto. Clearly the Anderson reference cited by the Examiner cannot be used to provide such automatic denial facility, which is inconsistent with a number of its basic teachings as cited previously.

Moreover, in support of an assertion of unobviousness, Appellant would respectfully show that Appellant's claimed

invention meets an important need long felt in the art, a compelling argument in support of patentability. As examples of such long felt and generally recognized need, Appellant presents the documents set forth in Items 1, 2 and 3 of Annex C to this Brief. These documents are:

Item 1. *A Summary of References Which Demonstrate Both the Novelty and Demand for Allcare's Privacy Service*

Item 2. *Online Healthcare Gets Candid Assessment at Berkeley Summit*

Item 3. *Privacy Technology Still Missing the Mark*

In reviewing the foregoing Items, it is dramatically evident that some of the most inquiring and influential minds in the field of medical record privacy have given much attention and thought to the importance of maintaining patient privacy while providing for legitimate controlled access to their medical records but without having achieved the *inspirational insight* manifest in Appellant's instant claims. While, in hindsight, such may seem more modest, it is well settled that although a "difference may have seemed slight (as has often been the case with some of history's great inventions, e.g., the telephone), [but] it may also have been the key to success and advancement in the art resulting from the invention." (*Jones et al v Hardy*, 220 USPQ 1021, Fed. Cir. 1984)(Underscoring Added). Appellant asserts that such is the case with the instant application.

In further support of unobviousness and consequent patentability of the instant claims, it has been observed authoritatively that "It is usually the application of old principles to new methods or articles of manufacture that involved patentable subject matter." (*In re Watter* 64 USPQ 571 CCPA 1945, at page 573) Moreover, as Judge Learned Hand observed, "It is the obvious when discovered and put to use that most often proves invention." (*H. C. White Co v Morton E. Converse & Son Co.*, 2 Cir., 20 F. 2d 311, 313)

As the Examiner is undoubtedly aware "Evidence of secondary considerations may often be the most probative and cogent evidence in the record. It may <u>often establish that an invention appearing to have been obvious in light of the prior art was not</u>." (*Stratoflex Inc v Aeroquip Corp*, 218 USPQ 879, Fed. Cir. 1983) (Underscoring added). Since it is well known that satisfaction of a well known and long felt need is an important secondary consideration, Appellant believes it evident that the subjects defined by the independent Claims 1 and 42 are unobvious and patentable not only over the Evans reference but over all other art of which Appellant is aware. Accordingly, it is respectfully requested that the rejection of Claims 1-2, 4-43 and 45-81 be withdrawn.

VII. THE ASSERTION MADE IN THE AUGUST 30, 2001 OFFICE ACTION AT PAGE 3, LINES 11-16 IS NOT PROPERLY READABLE AS DATA PROCESSING MEANS RESPONSIVE TO A REQUEST FOR PATIENT MEDICAL DATA FOR COMPARING SAID REQUEST WITH SAID CONDITIONS REQUIRED FOR ACCESS TO SAID DATA AND, WHEN SAID REQUEST FAILS TO COMPLY WITH SAID CONDITIONS, FOR DENYING ACCESS TO SAID DATA

Appellant finds no basis for the Examiner's assertion. The Examiner's assertion is a gross misreading of Evans, for the Examiner has attempted to equate an error loop that the inventor clearly intended to apply to those instances wherein an alphanumeric identifier was incorrectly entered into the system with a privacy mechanism in Appellant's system that protects the integrity of the information even in the instance that such identifier was accurately entered. The fact that the system in Evans was unable to process a request for a record whose identifier was entered in error is far from being a privacy mechanism.

Clearly, Evans had no such intention, and the Examiner's strained reading of the reference must be rejected. To accept the Examiner's argument would be equivalent to believing that the mere fact that when a caller incorrectly dials a person's telephone number the phone system is incapable of connecting that call, negates the novelty of a system that is capable of blocking

all incoming calls unless specific pre-conditions are first met. The two have little to do with one another.

VIII. RELATIONSHIPS AMONG PATIENT DATA ARE PATENTABLY DISTINCT FROM MEDICAL DATA INDIVIDUALLY RELATING TO EACH OF A PLURALITY OF PATIENTS.

Are relationships among patient data patentably indistinct from medical data individually relating to each of a plurality of patients? Please see the Examiner's assertion at lines 4-5 of the penultimate paragraphs on pages 4 of the Office Actions of November 21, 2000 and August 30, 2001 where it is said " . . . relationships among the data [are] considered . . . readable as medical data individually relating to each of a plurality of patients (see, abstract, lines 1-17)" (Underscoring added). For convenience of reference, the only relevant reference Appellant has been able to find in the abstract appears at lines 10-12 thereof where it is said "The system likewise permits instant, sophisticated analysis of patient data to identify relationships among the data considered." (Underscoring added).

In response to the Examiner's allegation, Appellant would respectfully show that relationships are very different from the individual data itself. Thus, the distance from the earth to the sun may be more than 300 times the distance from the earth to the moon, but one cannot tell from such a relationship what the actual distances or other characteristics (individual data) are.

Applying such to the situation at hand, relationships between patient data may be of little or no concern for privacy but the actual data for an individual patient may be extremely sensitive and require protection. Accordingly, it is deemed evident that the pronouncement made by the Examiner (and unsupported by definition, logic or reasoning) is in error and should not be upheld.

IX. WHETHER THE TERM "SUBSTANTIAL TEACHING" IS A PROPER BASIS FOR REJECTING CLAIMS UNDER 35 U.S.C. 103(a) AND HOW SPECIFICALLY DOES IT RELATE TO UNOBVIOUSNESS AND PATENTABILITY OF APPELLANT'S CLAIMS

The Examiner repeatedly used the expression "Evans substantially teaches" in rejecting claims 2 and 4-40 (and corresponding method claims). Appellant is not aware of any authority for rejections under 35 U.S.C. 103 based on "substantial teaching". However, if that phrase is intended to mean that the difference between the prior art and what Appellant has claimed would be obvious to one skilled in this art, it is noted that claims 2-40 are all drawn in dependent form to Claim 1; and since it is evident from the observations set forth in Sections I-VIII above that the subject matter of Claim 1 is unobvious over the Evans reference, it is not understood how the expression "substantially teaches" is applicable or is a valid basis for the rejection of Claims 2-40.

Claim 41 was rejected on the following basis: "As per claim 41, Evans discloses a system as claimed, further comprises means for allowing parties to advertise in the public portions of said system (see, figure 22)." Is the Examiner saying that he is rejecting Claim 41 under the provisions of 35 USC 102? If so, that would appear to be in direct contradiction with his admission that such is not disclosed by Evans as was stated in the Office Action of June 6, 2000 where, at page 3, it is said "...Evans does not specifically disclose a data processing means responsive to a request for patient medical data for comparing said request with said conditions required for access of said data and, when said request fails to comply with said conditions, for denying access to said data." (Underscoring added). If, on the other hand he is saying that the subject matter of Claim 41 is obvious in view of Evans, it is believed that such is in error for the reasons set forth above in connection with Claim 1 (to which Claim 41 is dependent).

The foregoing considerations have been presented specifically with respect to the system claims 1-41. However, since the method claims 42-81 correspond to the system claims 1-40, Appellant asserts these considerations support patentability of claims 42-81 as well.

As to the prior art, in Appellant's view and personal experience, the problems and failings of the present state-of-art in this area (specifically including systems such as disclosed in

Evans) are illustrative of the material and unobvious differences between a system that functions with generalized access through passwords and various forms of encryption, and a system such as that of Appellant which (though it may use passwords and encryption) requires prior individual informed consent by each patient, such informed consent satisfying specifically identified pre-conditions. Appellant's system affords the advantage of being fully able to operate in an extended area while providing each patient with the assurance, at his option, that his or her medical records will not be made available to others without his or her informed consent. Thus, it fills a need long felt in the art and is unobvious and patentable thereover.

As mentioned above, Claims 2-41 and 43-81 are dependent to Claims 1 and 42 respectively and therefore are deemed to patentably distinguish over the prior art for the reasons set forth above in respect to Claims 1 and 42. They severally define sub-combinations which include additional elements and steps to further define over the art. These are discussed in the foregoing section relating to Grouping of Claims. However, attention is directed to particularly cogent examples defined by Claims 3 and 44 which emphasize the requirement for individual prior informed consent by patients whose records are involved before such record can be accessed. Further emphasis thereof is represented by Claims 24 and 65 which particularize on the preferred mode for contacting a patient to request approval for

release of patient data. Accordingly, it is deemed evident that Claims 2-41 and 43-81 are unobvious over the art and should be allowed.

SUMMARY

By the Examiner's own statements, the *Evans* patent fails to disclose the subject matter of Appellant's claims as evidenced by the following quotation "...Evans does not specifically disclose a data processing means responsive to a request for patient medical data for comparing said request with said conditions required for access of said data and, when said request fails to comply with said conditions, for denying access to said data." Moreover, for the reasons set forth above, the Anderson articles neither teach nor suggest the subject matter of Appellant's systems and methods. In addition, Appellant finds no authoritative basis for combining Evans with the teachings of Anderson; and to the contrary, finds that the two references are **NOT** properly combinable as suggested by the Examiner. Hence, it is evident that the rejections made are in error, that the rejections should be reversed, and that the claims on appeal should be allowed.

Respectfully,

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CERTIFICATE OF MAILING

I hereby certify that the above-noted paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D. C. 20231, on 29 November, 2001.

Andrew M. Hassell

APPENDIX A

CLAIMS UNDER APPEAL

1. A medical data base supervisory control system comprising:

(a) at least one data base including medical data individually relating to each of a plurality of patients,

(b) means including interconnected computers for requesting and accessing said medical data,

(c) means for identifying medical data for each of said patients with conditions required for accessing said medical data, and

(d) data processing means responsive to a request for patient medical data for comparing said request with said conditions required for access to said data and, when said request fails to comply with said conditions, for denying access to said data.

2. A system of Claim 1 further including means for authenticating the identity of the requesting party.

3. The system of Claim 2 further including means to prevent access to information concerning medical records by any party without the prior authorization of the patient about whom such records pertain.

4. The system of Claim 1 further including means for tentatively identifying records fulfilling criteria specified in said request for medical data.

5. The system of Claim 4 further including means for

authenticating identity of said patients.

6. The system of Claim 1 wherein said means for requesting said medical data includes means for indicating what part of said records is desired.

7. The system of Claim 1 wherein said means for requesting access to said medical records includes means for indicating the reason said records are being requested.

8. The system of Claim 1 further including means for identifying records fulfilling said request with data symbolic of patient identity.

9. The system of Claim 8 wherein said means for identifying records fulfilling said request further include data symbolic of medical symptoms or reason for patient visit.

10. The system of Claim 8 wherein said means for identifying records fulfilling said request further include data symbolic of types of diagnostic tests performed.

11. The system of Claim 10 wherein said means for identifying records fulfilling said request further include data symbolic of the attributes, levels or findings indicated within said diagnostic tests.

12. The system of Claim 8 wherein said means for identifying records fulfilling said request further include data symbolic of modes of treatment or medical services rendered.

13. The system of Claim 8 wherein said means used for identifying records fulfilling said request further include data

symbolic of any ancillary services rendered.

14. The system of Claim 8 wherein said means used for identifying records fulfilling said request further include data symbolic of attending physician identity.

15. The system of Claim 8 wherein said means for identifying records fulfilling such request further include data symbolic of date of care.

16. The system of Claim 1 wherein said means for requesting and accessing said medical data includes means for indicating a "standing order" that will automatically initiate an attempt to retrieve certain predetermined types of medical data under specific pre-specified circumstances.

17. The system of Claim 1 wherein said conditions required for accessing said medical data includes an indication of the names of each of the parties who's permission must be obtained prior to the release of the medical data.

18. The system of Claim 17 wherein said conditions required for accessing said medical data further includes an indication of the charge that will be assessed by the holder of such medical data for the part, or in the form, specified by the requesting party.

19. The system of Claim 17 wherein said conditions for accessing said medical data includes means indicating the time following the receipt of all approvals that will be required for

the delivery of such medical data to the requesting party.

20. The system of Claim 1 wherein said at least one data base includes a firewall limiting access to searching such data base solely to those parties who are authorized to do so.

21. The system of Claim 1 wherein said means for identifying medical data fulfilling criteria specified in a request include means for producing an indicia of the degree to which patient data match said criteria specified in said request.

22. The system of Claim 1 including means for a patient to grant permission for the release of his/her medical data.

23. The system of Claim 22 wherein said at least one data base includes billing means having access to said medical data.

24. The system of Claim 22 wherein said means for a patient to grant permission includes data symbolic of the identity of said patient and data symbolic of the preferred means for contacting said patient to request access to and release of said patient's medical data.

25. The system of Claim 23 wherein said means for a patient to grant permission includes data symbolic of rules to be followed in the event time elapses before such permission is granted in the case of predetermined types of requests for said medical data.

26. The system of Claim 1 further including means for identifying the party requesting access to said medical data.

27. The system of Claim 26 further including means for

authenticating the identity of each party having right of approval for release of said medical data.

28. The system of Claim 27 further including means for producing an indicia that all required approvals for the release of said medical data have been secured.

29. The system of Claim 28 further including means for producing an indicia of the required approvals for the release of said medical data that have not been secured or that have been specifically declined.

30. The system of Claim 20 further including data index means and on-line memory cache means for physically disconnecting said at least one data base from said data index means, online memory cache means and all other outside parties except during batch process of uploading pre-designated and fully-approved requests for medical data.

31. The system of Claim 30 further including interface engine means enabling a search agent means to index said at least one data base of medical data.

32. The system of Claim 1 further including means for billing said requesting party for a charge related to access to the medical data.

33. The system of Claim 1 further including online memory cache means and means for delivering medical data to a requesting party including means for transmitting requested medical data held in digital form to said online memory cache means.

34. The system of Claim 33 wherein said online memory cache means includes a firewall limiting access to said memory cache means exclusively to authorized users.

35. The system of Claim 33 further including means for producing an indicia that said requested medical data have been received in said online memory cache means and are being held there for download by said requesting party.

36. The system of Claim 34 further including means for said requesting party to enter through said firewall and download said medical data from said memory cache means.

37. The system of Claim 1 including means for delivering medical data to a requesting party.

38. The system of Claim 37 further including means for informing said requesting party when medical data is in a non-digital form and the mode of available delivery.

39. The system of Claim 1 further including means for encrypting all communications within the system.

40. The system of Claim 1 further including security log means for retaining an audit trail with regard to all of the communications within said system.

41. The system of Claim 1 further including public portions, and comprising means for allowing parties to advertise in said public portions of said system

42. A method of controlling access to medical data in a medical data base comprising:

(a) maintaining at least one data base including medical data individually relating to each of a plurality of patients,

(b) identifying medical data for each of said patients with indicia indicative of conditions required for access to said medical data,

(c) selectively introducing requests for access to said data through an interconnected computer input terminal,

(d) comparing said requests with said conditions; and, when said requests fail to comply with said conditions, automatically denying access to said data.

43. The method of Claim 42 further including a step of authenticating identities of parties making said requests.

44. The method of Claim 43 further includes the step of rejecting requests for information concerning medical records by any party without the prior authorization of the patient about whom such records pertain.

45. The method of Claim 42 further including the step of tentatively identifying records fulfilling criteria specified in said requests for medical data.

46. The method of Claim 45 further including a step of authenticating identities of said patients.

47. The method of Claim 42 further including steps of requesting said medical data and indicating what part of said data is desired by said requesting party.

48. The method of Claim 42 further including steps of

requesting access to said medical records and indicating a reason said records are being requested.

49. The method of Claim 42 including a step of ensuring that records fulfilling said requests include data symbolic of patient identities.

50. The method of Claim 49 wherein said step of identifying records fulfilling said requests further include data symbolic of medical symptoms or reason for patient visit.

51. The method of Claim 49 wherein said step of identifying records fulfilling said requests further include data symbolic of types of diagnostic tests performed.

52. The method of Claim 51 wherein said step of identifying records fulfilling said requests further include data symbolic of the attributes, levels or findings indicated within said diagnostic tests.

53. The method of Claim 49 wherein said step of identifying records fulfilling said requests further include data symbolic of modes of treatment or medical services rendered.

54. The method of Claim 49 wherein said step of identifying records fulfilling said requests further include data symbolic of the ancillary services rendered.

55. The method of Claim 49 wherein said step of identifying records fulfilling said requests further include data symbolic of attending physician identity.

56. The method of Claim 49 wherein said step of identifying

records fulfilling said requests further include data symbolic of date of care.

57. The method of Claim 42 wherein said step of selectively introducing requests for access to said medical data includes a step of indicating a "standing order" that will automatically initiate an attempt to retrieve certain predetermined types of medical data under specific pre-specified circumstances.

58. The method of Claim 42 wherein said conditions required for accessing said medical data include a step of indicating names of each party who's permission must be obtained prior to release of said medical data.

59. The method of Claim 58 wherein said conditions required for accessing said medical data include an indication of the charge that will be assessed by the holder of such medical data for the part, or in the form, specified by the requesting party.

60. The method of Claim 58 wherein said conditions for accessing said medical data include a step of indicating the time following the receipt of all approvals that will be required for the delivery of such medical data to the requesting party.

61. The method of Claim 42 wherein maintaining said at least one data base includes maintaining a firewall limiting access to searching said data base solely to those parties who are authorized to do so.

62. The method of Claim 42 further including providing a data index, and wherein identifying medical data fulfilling

criteria specified in a request includes a step of producing an indicia of the degree to which data listed in said data index match said criteria specified in said request.

63. The method of Claim 42 including a step of providing for a patient to grant permission to release of such medical data.

64. The method of Claim 63 wherein said step of identifying medical data includes a step of billing for access to said medical data.

65. The method of Claim 63 wherein said step of providing for a patient to grant permission includes data symbolic of the identity of said patient and data symbolic of a preferred means for contacting said patient to request access to and to release of said patient's medical data.

66. The method of Claim 64 wherein said step of providing for a patient to grant permission includes providing data symbolic of rules to be followed in the event time elapses before said permission is granted in the case of pre-determined types of requests for said medical data.

67. The method of Claim 42 further including a step of identifying a party requesting access to said medical data.

68. The method of Claim 67 further including a step of authenticating identity of each party with a right of approval to release of said medical data.

69. The method of Claim 68 further including a step of producing an indicia that all required approvals for release of

said medical data have been secured.

70. The method of Claim 69 further including a step of producing an indicia of approvals required for release of said medical data that have not been secured, or that have been specifically declined.

71. The method of Claim 61 further including steps of providing a data index and online memory cache, and physically disconnecting said at least one data base from said data index, said online memory cache and all other outside parties except during batch process of uploading pre-designated and fully-approved requests for medical data.

72. The method of Claim 71 further including a step of providing an interface engine for search agent means to index said at least one data base of medical data.

73. The method of Claim 42 further including a step of billing a requesting party for a charge related to delivery of medical data.

74. The method of Claim 42 further including steps of providing an online memory cache and delivering medical data to a requesting party and transmitting records in digital form to said online memory cache.

75. The method of Claim 74 further including providing a firewall limiting access to said memory cache exclusively to authorized users.

76. The method of Claim 74 further including a step of

producing an indicia that requested medical data have been received in said online memory cache and are being held there for download by a requesting party.

77. The method of Claim 75 further including a step of permitting a properly credentialed requesting party to enter through said firewall and download said medical data from said memory cache.

78. The method of Claim 42 including a step of delivering records to the requesting party.

79. The method of Claim 78 further including a step of informing a requesting party when medical data is in a non-digital form and the mode of such delivery.

80. The method of Claim 42 further including a step of encrypting selected communications within said system.

81. The method of Claim 42 further including a step of creating a security log and retaining an audit trail with regard to all of the communications between parties using said system.

APPENDIX B

AUTHORITIES ON WHICH RELIED

Appellant relies upon the following authorities:

1. In re Fritch 23 USPQ 2d 1780 (Fed. Cir., 1992) "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. . . . It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." (Page 1783)

2. Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company 221 USPQ 481 (Fed. Cir., 1984). "The claimed invention must be considered as a whole, and the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness of making the combination. (At page 488)

3. In re Lunsford 148 USPQ 721, 725 "Moreover as a matter of law under 35 U.S.C.103, the examiner **must** substantiate his 'suspicions' on the basis of facts drawn from proper prior art. The issue to be resolved requires more than 'suspicions' it requires facts." and "it is not realistic . . . within the framework of section 103 to pick and choose from any one

reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. (Emphasis added).

4. In re Rijckaert 28 USPQ 2d, 1955 (Fed. Cir., 1993) " . . in rejecting claims under 35 U.S.C. 103, the Examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant" . . "when the PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it **must** indicate where such a teaching or suggestion appears **in the reference**" (Emphasis added) . . . "The mere fact that a certain thing may result from a given set of circumstances is not sufficient . . ."

5. In re Soli 137 USPQ 797, 801 (passage is recited above in text of arguments) "When, as in the instant case, the Patent Office finds, in the words of 35 U.S.C. 103, 'differences between the subject matter sought to be patented and the prior art,' it may not without some basis in logic or scientific principle, merely allege that such differences are either obvious or of no patentable significance and thereby force an appellant to prove conclusively that it is wrong." (Underscoring added).

6. Minnesota Mining & Manufacturing Co v. Johnson & Johnson Orthopaedics 24 USPQ 2d 1321 (Fed. Cir., 1992) "In defining the meaning of key terms in a claim, reference may be

had to the specification, the prosecution history, prior art and other claims . . ."(Page 1327)

7. Renishaw PLC v Marposs Societa Per Azioni 48 USPQ 2d 1117 (Fed. Cir., 1998) " . . . one may look to the written description to define a term already in a claim limitation, for a claim must be read in view of the specification of which it is a part." (Page 1120).

8. In re Jones, 21 USPQ 2d 1941 (Fed. Cir., 1992) "Before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so . . . *In re Fine*, 5 USPQ 2d 1596, 1598-99 (Fed Cir 1988)" [at 1943]. The prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compound." [at 1944] (Emphasis added).

9. In re Fine, 5 USPQ 2d 1596, 1598-99 (Fed. Cir., 1988) Please see the quotation under In re Jones immediately above.

10. Jones et al v Hardy, 220 USPQ 1021 (Fed. Cir., 1984) ". . . difference may have seemed slight (as has often been the case with some of history's great inventions, e.g., the telephone), [but] it may also have been the key to success and advancement in the art resulting from the invention." (Emphasis added).

11. In re Watter 64 USPQ 571 (CCPA, 1945) at page 573 "It is usually the application of old principles to new methods

or articles of manufacture that involved patentable subject matter."

12. H. C. White Co v Morton E. Converse & Son Co., 2 Cir., 20 F. 2d 311, 313. Judge Learned Hand observes: "It is the obvious when discovered and put to use that most often proves invention."

13. Stratoflex Inc v Aeroquip Corp, 218 USPQ 879, (Fed. Cir. 1983) "Evidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not.

14. In re Zurko, 42 USPQ 2d 1476 (Fed. Cir. 1997) "In so erring, the Board impermissibly used hindsight to arrive at the claimed invention. . . To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." (Emphasis added).

15. In re Zurko, 59 USPQ2d 1693, (Fed. Cir. 2001) "This assessment of basic knowledge and common sense was not based on any evidence in the record and, therefore, lacks substantial evidence support"; and "With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or

experience - or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings." (Underscoring added).

16. In re Sernaker, 217 USPQ 1 (Fed. Cir., 1983), Page 6. "The lesson of this case appears to be that prior art references in combination do not make an invention obvious unless something in the prior art references would suggest the advantage to be derived from combining their teachings."

17. Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company 221 USPQ 481 (Fed. Cir., 1984). Moreover, in order for references to be properly combinable, there must be something in at least one of them, or in the prior art as a whole, that suggests the desirability, and thus the obviousness, of making the combination.

18. W. L. Gore and Associates, Inc. V Garlock, Inc. 220 USPQ 303, 312, which states "To imbue one of ordinary still in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher."

APPENDIX C

ARTICLES EVIDENCING LONG FELT UNMET NEED

Item 1: *A Summary of References Which Demonstrate Both the Novelty and Demand for Allcare's Privacy Service*

Item 2: *Online Healthcare Gets Candid Assessment at Berkeley Summit*

Item 3: *Privacy Technology Still Missing the Mark*

Comment: In reviewing the foregoing Items, it is dramatically evident that many of the most inquiring and influential minds have given much attention and thought to the importance of maintaining patient privacy while providing for legitimate controlled access to their medical records yet without having achieved the *inspirational insight* manifest in Appellant's claimed subjects. (Important felt need not previously met)

PLEASE NOTE:

(Copies of these articles were included with the Original Brief)